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TRANSMITTAL OF APPEAL BRIEF (Large Entity)

Docket No.
Implex-13

In Re Application Of: Bruce Robie et al.

Application No.	Filing Date	Examiner	Customer No.	Group Art Unit	Confirmation No.
10/035,863	December 31, 2001	Philogene, Pedro	28581	3732	4928

Invention:

INSTRUMENT SYSTEM FOR PREPARING A DISC SPACE BETWEEN ADJACENT VERTEBRAL BODIES TO RECEIVE A REPAIR DEVICE

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Signature

Dated: September 30, 2004

Paul A. Schwarz, Esq.
Registration No. 37,577

Duane Morris LLP
P.O. Box 5203
Hamilton, New Jersey 08619-5203
Tel: (609) 631-2446
Fax: (609) 631-2401

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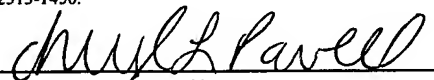
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES



In re application of: Bruce Robie et al.	Examiner: Philogene, Pedro
Serial No.: 10/035,863	Group Art Unit: 3732
Filed: December 31, 2001	Docket No.: Implex-13
For: INSTRUMENT SYSTEM FOR PREPARING A DISC SPACE BETWEEN ADJACENT VERTEBRAL BODIES TO RECEIVE A REPAIR DEVICE	Date: September 30, 2004

I CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE U.S. POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO MAIL STOP APPEAL BRIEF - PATENTS, THE COMMISSIONER FOR PATENTS, P.O. BOX 1450, ALEXANDRIA, VA 22313-1450.


Cheryl L. Powell

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APPEAL BRIEF

This is an appeal from the Office action mailed on January 30, 2004 finally rejecting claims 1, 15, 16, 21-23 and 25-34 in the application. This Brief is accompanied by the requisite fees set forth in 37 CFR 1.17(c). Authorization is hereby given for any additional fees due and owing in connection with this Brief or for any overpayment credit to be charged to Deposit Account No. 50-2061.

REAL PARTY IN INTEREST

Zimmer Trabecular Metal Technology, Inc. is the real party in interest in the present appeal.

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**OTHER RELATED PRIOR AND PENDING APPEALS,
INTERFERENCES, AND JUDICIAL PROCEEDINGS**

There are no other prior and pending appeals, interferences, and judicial proceedings known to the appellant's legal representative, appellant, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

STATUS OF CLAIMS AND IDENTIFICATION OF CLAIMS ON APPEAL

Claims 1-34 are pending.

Claims 17 and 24 stand objected to.

Claims 1, 15, 16, 21-23 and 25-34 stand finally rejected.

Claims 1, 15, 16, 21-23 and 25-34 are appealed herein.

STATUS OF AMENDMENTS

The amendment filed on April 30, 2004, which proposes to cancel withdrawn claims 2-14 and 18-20, has been entered for purposes of appeal.

**EXPLANATION OF THE INVENTION
OF THE INDEPENDENT CLAIMS**

Independent claim 1 is directed to an instrument system for preparing the disc space between adjacent vertebral bodies thereby allowing a repair device to be received in the prepared space. The instrument system comprises one or more distractors which are used for determining the appropriate size of the repair device to be inserted in the disc space.

Independent claim 15 is directed to a distractor for use in a system for preparing the disc space between adjacent vertebral bodies thereby allowing a repair device to be received in the prepared space.

The distractors referred to in independent claims 1 and 15 are constructed to provide a certain amount of interdiscal distraction that restores the natural lordosis of the lumbar and cervical spine. Lordosis requires that the anterior height of the disc space be greater than the posterior height. Once the appropriate distractor has been selected, it is inserted into the disc space to distract the vertebral bodies.

As described on pages 5-6, paragraph [0029] and shown in FIGS. 1A-1C, each distractor 10 comprises a body section 11 that includes a tapered portion 16. The tapered portion is defined by converging superior and inferior wall portions 21, 22, and converging side wall portions 23, 24. The converging superior, inferior, and side wall portions 21, 22, 23, 24 meet at a posterior wall 25.

As described on page 6, paragraph [0031] (still referring to FIGS. 1A-1C), the converging superior and inferior wall portions 21, 22 define a taper angle θ that matches the tapered portion 16 of the body section 11 to the lordosis of the repair device to be used in the disc space. As shown in FIG. 1D, the tapered body portion 16 of the distractor 10 reestablishes the natural lordosis of the disc space, and prepares a broad contact area for the repair device, which is unlike the disc space resulting from prior art distractors.

GROUND OF REJECTION

There are two grounds of rejection presented for review in this appeal.

Claims 1, 15, 16, 23, 25, and 29 stand rejected under 35 USC 102(b) as being anticipated by U.S. Patent 5,722,977 to Wilhelmy (Wilhelmy).

Claims 21, 22, and 26-34 stand rejected under 35 USC 103(a) as being unpatentable over Wilhelmy in view of U.S. Patent 6,648,895 to Burkus *et al.* (Burkus).

ARGUMENT

I. REJECTION UNDER 35 USC 102(b)

Claims 1, 15, 16, 23, 25, and 29:

Claims 1, 15, 16, 23, 25, and 29 stand rejected under 35 USC 102(b) as being anticipated by Wilhelmy. Claim 1 is representative of the claims rejected under 35 USC 102(b) using Wilhelmy and reads as follows:

An instrument system for preparing a disc space between adjacent vertebral bodies to receive a repair device, the instrument system comprising:

at least one distractor including a tapered body section for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines, the tapered body section formed by:

an end wall;
a first pair of opposing wall portions converging toward the end wall; and
a second pair of opposing wall portions converging toward the end wall.

The Examiner contends that Wilhelmy describes applicant's instrument system comprising at least one distractor. In particular, the examiner contends that Wilhelmy in column 5, lines 44-67 describes a spacer that has "top and bottom surfaces 19, 21, and 19' and 21' converging toward the end wall."

It is respectfully submitted, however, that Wilhelmy does not anticipate applicant's instrument system because Wilhelmy does not expressly or inherently describe each element of

claim 1. Anticipation of a claim requires that the cited prior art reference must disclose every element of the claim. "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference."

Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed.Cir. 1987).

With respect to claim 1, Wilhelmy does not expressly or inherently describe a distractor having Applicant's claimed first and second pairs of opposing wall portions converging toward the distractor's end wall. In contrast, FIGS. 11 and 12 of Wilhelmy clearly show a spacer having only one pair of opposing wall portions 19' and 21' that converge toward the spacer's end wall

22. Moreover, Wilhelmy states in column 5, lines 52-60:

As shown, the tapered wedge member 17...is formed with parallel top and bottom surface portions 19 and 21, respectively, and top and bottom surface portions 19' and 21' converging anteriorly toward and intercepted by end surface 22...The opposed left and right side surfaces 23 and 24, as seen in FIGS. 8-12, are parallel and extend anteriorly from base 16 and are intercepted by the anterior end surface 22.

Hence, the specification of Wilhelmy clearly describes that the top and bottom surfaces portions 19 and 21 are parallel to one another and therefore, these surface portions can not be converging toward the end surface 22, as erroneously contended. The opposing left and right side surfaces 23 and 24 of the Wilhelmy spacer are also parallel to one another, therefore these surface portions can not be converging toward the end surface 22 either. Consequently, Wilhelmy merely describes a spacer having only one pair of opposing wall portions converging toward the end surface thereof. Since Wilhelmy fails to expressly or inherently describe each element of claim 1, there is no anticipation by Wilhelmy.

In view of the foregoing, claims 1, 15, 16, 23, 25, and 29 are patentable over Wilhelmy under 35 USC 102(b).

II. REJECTION UNDER 35 USC 103(a)

Claims 21, 22, and 26-34:

Claims 21, 22, and 26-34 stand rejected under 35 USC 103(a) as being unpatentable over Wilhelmy in view of Burkus.

Claim 21 is representative of the claims rejected under 35 USC 103(a) using Wilhelmy in view of Burkus and reads as follows:

The instrument system according to claim 1, wherein the at least one distractor includes a longitudinal axis and at least one of the first pair of wall portions includes a groove that extends generally perpendicular to the longitudinal axis.

The Examiner contends that Wilhelmy teaches all the limitations recited in claims 21, 22, and 26-34 except for the T-shape slot defining inwardly facing locking flanges, which are taught by Burkus.

A claimed invention is *prima facie* obvious when three basic criteria are met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine teachings. *See In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992); *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988). Second, there must be a reasonable expectation of success. *See In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Third, the prior art reference or combined references must teach or suggest all the claim limitations. *See In re Royka*, 490 F. 2d 981, 180 USPQ 580 (CCPA 1974).

Claim 21 depends directly from claim 1 and therefore includes all the limitations of claim 1. As discussed above in section I of the ARGUMENT, Wilhelmy fails to disclose, teach or suggest all the limitations of claim 1, particularly the first and second pairs of opposing wall portions converging toward the end wall of the distractor body. In addition, Wilhelmy fails to teach or suggest the groove of claim 21.

Burkus does not cure the deficiencies of Wilhelmy as Burkus fails to disclose, teach or suggest the first and second pairs of opposing wall portions converging toward the end wall of the distractor body, as called for in claim 21 by virtue of its dependence upon claim 1. For at least this reason, Wilhelmy in view of Burkus do not teach or suggest all the limitations of claim 21.

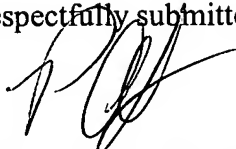
In view of the foregoing, claims 21, 22, and 26-34 are patentable over Wilhelmy in view of Burkus under 35 USC 103(a).

CONCLUSION

It has been shown that the claimed invention distinguishes over the express and implied teachings of the prior art cited of record in the application. In addition, Applicant respectfully submits that there is no suggestion or motivation, in Wilhelmy, Burkus, the other references cited of record in the application, or in the knowledge generally available to one of ordinary skill in the art, to modify the spacer of Wilhelmy or the spacer of Wilhelmy in view of Burkus, to include a second pair of opposing wall portions converging toward the end surface of the spacer. Therefore, it would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the Wilhelmy spacer or the Wilhelmy in view of Burkus spacer, to include a second pair of opposing wall portions converging toward the end surface of the

spacer. Hence, appellant respectfully requests that the Board reverse the examiner and direct that the application proceed to issue.

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'P. Schwarz', written over the words 'Respectfully submitted,'.

PAUL A. SCHWARZ, Esq.
Reg. No. 37,577

September 30, 2004

Paul A. Schwarz, Esq.
Duane Morris LLP
P.O. Box 5203
Hamilton, New Jersey 08619-5203
(609) 631-2446 - telephone
(609) 631-2401 - facsimile

**APPENDIX A
CLAIMS IN APPEAL**

1. (Previously Presented) An instrument system for preparing a disc space between adjacent vertebral bodies to receive a repair device, the instrument system comprising:

at least one distractor including a tapered body section for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines, the tapered body section formed by:

an end wall;

a first pair of opposing wall portions converging toward the end wall; and

a second pair of opposing wall portions converging toward the end wall.

2. (Cancelled)

3. (Cancelled)

4. (Cancelled)

5. (Cancelled)

6. (Cancelled)

7. (Cancelled)

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Cancelled)

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15.(Previously Presented) A distractor for use in a system that prepares a disc space between adjacent vertebral bodies to receive a repair device, the distractor comprising a tapered body section for distracting the vertebral bodies in a manner that restores natural lordosis of the lumbar and cervical spines, the tapered body section formed by:

an end wall;

a first pair of opposing wall portions converging toward the end wall; and

a second pair of opposing wall portions converging toward the end wall.

16.(Original) The distractor according to claim 15, wherein the distractor further includes a connector section opposite the body section, the connector section for coupling a handle to the distractor.

17.(Previously Presented) The distractor according to claim 16, wherein the connector section includes a detent element.

18.(Cancelled)

19.(Cancelled)

20.(Cancelled)

21.(Previously Presented) The instrument system according to claim 1, wherein the at least one distractor includes a longitudinal axis and at least one of the first pair of wall portions includes a groove that extends generally perpendicular to the longitudinal axis.

22.(Previously Presented) The instrument system according to claim 1, wherein the at least one distractor includes a longitudinal axis and each of the first pair of wall portions includes a groove that extends generally perpendicular to the longitudinal axis.

23.(Previously Presented) The instrument system according to claim 1, wherein the at least one distractor further includes a connector section opposite the body section, the connector section for coupling a handle to the distractor.

24.(Previously Presented) The instrument system according to claim 23, wherein the connector section includes a detent element.

25.(Previously Presented) The instrument system according to claim 23, wherein the connector section includes a female coupling member.

26.(Previously Presented) The instrument system according to claim 25, wherein the female coupling member is formed by a T-shape slot.

27.(Previously Presented) The instrument system according to claim 26, wherein the T-shape slot defines inwardly facing locking flanges.

28.(Previously Presented) The instrument system according to claim 26, wherein the T-shape slot defines a surface, the surface including a bore for receiving a pilot pin formed at an end of the handle.

29.(Previously Presented) The distractor according to claim 16, wherein the connector section includes a female coupling member.

30.(Previously Presented) The distractor according to claim 29, wherein the female coupling member is formed by a T-shape slot.

31.(Previously Presented) The distractor according to claim 30, wherein the T-shape slot defines inwardly facing locking flanges.

32.(Previously Presented) The distractor according to claim 31, wherein the T-shape slot defines a surface, the surface including a bore for receiving a pilot pin formed at an end of the handle.

33.(Previously Presented) The distractor according to claim 15, further including a longitudinal axis, wherein at least one of the first pair of wall portions includes a groove that extends generally perpendicular to the longitudinal axis.

34.(Previously Presented) The distractor according to claim 15, further including a longitudinal axis, wherein each of the first pair of wall portions includes a groove that extends generally perpendicular to the longitudinal axis.